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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

United States of America,

Plaintiff,

v.

Mark Schena,

Defendant.

CASE NO. 5:20-cr-00425-EJD

DEFENDANT'S BRIEF RE EVIDENTIARY OBJECTIONS REGARDING GOVERNMENT'S REMAINING WITNESSES OR EVIDENCE

I. INTRODUCTION

The government has indicated it is likely to complete its evidence on August 19, 2022, which includes calling Alex Kondratenko and to move into evidence certain exhibits from Blue Cross Blue Shield ("BCBS"), to move into evidence certain documents from Aetna, to call Michael Petron and potentially introduce certain summary charts from him, and to call as a witness Dr. Susan Zullo from the Food and Drug Administration ("FDA") and move into evidence certain exhibits relating to Arrayit's submission of an application of emergency use authorization ("EUA"). The defendant Mark Schena submits this brief to expedite issues relating to this evidence. To be clear, Mr. Schena may have additional objections and nothing in his effort to efficiently raise these now waives his right to make additional objections, including as to the evidence identified below.

II. THE COURT SHOULD LIMIT SCOPE OF TESTIMONY AND PRECLUDE ADMISSION OF CERTAIN PRIVATE INSURANCE DOCUMENTS

The government apparently intends to admit evidence relating to BCBS and Aetna's internal investigation and audits regarding certain of Arrayit's claims submitted for insurance payment. Mr. Schena objects to Exhibit No. 1101, which is an internal audit and investigation report by Aetna, as well as Exhibits Nos. 1109-10 and 1114-15, which are notes or internal investigation or audit reports by BCBS. These documents do not meet the foundational requirements to qualify as business records under either Fed. R. Evid. ("FRE") 803(6) or its corollary rule, FRE 902(11) because they were the results of audits and investigations, in the case of BCBS over a year after charges were filed, and without sufficient evidence they were prepared in the ordinary course of business. Further, the records both constitute and contain hearsay not subject to an exception. As to Mr. Kondratenko, it does not appear from his interview report that he himself engaged in the audit to determine medical necessity of the selected claims for Arrayit. Accordingly, he lacks the personal knowledge to testify as to a determination made by others at BCBS and thus cannot testify as to the results of that audit as it is inadmissible hearsay without an exception.

Under FRE 803(6), records of regularly conducted activity are not excluded under the rule against hearsay if: (a) "the record was made at or near the time by—or from information transmitted by—someone with knowledge"; (b) "*the record was kept in the course of a regularly conducted activity* of a business,

organization, occupation, or calling, whether or not for profit"; (c) *making the record was a regular practice of that activity*"; (d) "all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification"; and (e) "the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness." FRE 803(6)(A)-(E) (emphasis added); *see also U-Haul, Int'l., Inc. v. Lumbermens Mut. Cas. Co.*, 576 F.3d 1040, 1043 (9th Cir. 2009). FRE 902(11) operates in tandem with Rule 803(6) "by providing a mechanism through which business records can be authenticated short of live foundational testimony." *U.S. v. Weber*, 574 F. Supp. 3d 791, 792 (D. Montana 2021).

The Ninth Circuit has held that reports prepared by an accounting firm based upon a "special audit ordered in response to the Trustees' suspicion of irregularities" did not qualify as a business records under FRE 803(6) because they were not prepared in the ordinary course of the firm's accounting business. *Paddack v. Dave Christensen, Inc.*, 745 F.2d 1254, 1258 (9th Cir. 1984). Further, the Ninth Circuit in *Paddack* also explained another problem with admissibly under FRE 803(6) in that they were "prepared in anticipation of litigation"—*i.e.*, after there was a suspicion of wrongdoing. *Id*. at 1258-59. "[A] document prepared for purposes of litigation is not a business record because it is lacking in trustworthiness." *Id*. (citing *Clark v. City of Los Angeles,* 650 F.2d 1033, 1036-37 (9th Cir. 1981); *Palmer v. Hoffman*, 318 U.S. 109, 87 L. Ed. 645, 63 S. Ct. 477 (1943) (internal citations omitted)); *see also Timberlake Constr. Co. v. U.S. Fid. & Guar. Co.*, 71 F.3d 335, 342 (10th Cir. 1995) ("[i]t is well-established that one who prepares a document in anticipation of litigation is not acting in the regular course of business.").

Consistent with this authority, a district court in the Ninth Circuit recently held that one who prepares a document as a result of an internal investigation is not acting in the regular course of business. *See U.S. v. Babichenko*, Case No. 1:18-cr-00258-BLW, 2022 WL 1591891 (D. Idaho May 19, 2022). In a situation very similar to the present case, the court in *Babichenko* analyzed records which the government sought to admit and certify as business records pursuant to FRE 803(6) and 902(11). Although the Rule 902(11) certification at issue "appear[ed] to be sufficient to meet the requirements" of both rules at first blush, the company whose records the government sought to admit and authenticate issued a follow-up

email to the purported certification, noting that the records were "the product of an internal investigation, requiring analytical efforts beyond merely collecting records maintained in the ordinary course of business." *Id.* at *2. The court in *Babichenko* agreed that the language "raise[d] concerns regarding whether the spreadsheets include information based on analytical efforts beyond merely collecting records maintained in the ordinary course of business," and sustained the defendants' objection to the records' admissibility under FRE 803(6) and 902(11).

In this case, both Aetna's and BCBS's audit and internal investigation notes and reports were based upon analysis that was undertaken after some suspicion was raised regarding Arrayit's claims. Like the audit in *Paddack* or investigation in *Babichenko*, there is no evidentiary basis to conclude these were conducted as part of the regular business activities of the private insurance companies. Indeed, although Aetna closed its investigation with no further action, BCBS ended up preparing a letter sent to Arrayit threatening litigation, underscoring that both of these efforts were done, in part, in anticipation of potential litigation regarding Arrayit's submission of claims. As such, Exhibit No. 1101, and Exhibits Nos. 1109-10 and 1114-15 are inadmissible under FRE 902(11) and 803(6).

Nor can the government skirt this issue by relying on the testimony of Mr. Kondratenko, who is an investigator at BCBS. It appears that Mr. Kondratenko oversaw BCBS's investigation and audit but did not himself actually review Arrayit's claims to make a determination of whether there was sufficient information in those claims to meet BCBS's criteria for medical necessity. Rather, a medical director at BCBS made that a determination as did a separate external body from BCBS. Mr. Kontradenko thus lacks personal knowledge to testify as to the determination of medical necessity of Arrayit's claims submitted to BCBS and any effort to relay through Mr. Kontradenko the determination of others would be inadmissible hearsay not subject to any exception. Accordingly, the Court should preclude Mr. Mr. Kondratenko from testifying as to the results of BCBS's audit and investigation.

III. SUMMARY EXHIBITS

The government appears to intend to call Michael Petron to testify as his review of certain records and preparation of various summary charts, presumably under Rule 1006. The predicate for that rule is that the evidence summarized "cannot be conveniently examined in court." FRE 1006. Further, a Rule

1006 summary exhibit must be based upon admissible evidence. *See United States v. Johnson*, 594 F.2d 1253, 1255 (9th Cir. 1979) ("We hold that under this Rule the proponent of the summary must establish that the underlying materials upon which the summary is based are admissible in evidence.").

In this case, at least a few of the "summary charts" are merely demonstratives of exhibits that have already been repeatedly examined in Court by the government through various witness. This includes Exhibits 20, 22, 25, and 38. Further, Exhibit Nos. 44 and 45 appear to be the same excerpt of a single page from a 9-page document. Rule 1006 does not support admission of demonstrative exhibits from documents that have been or can be readily discussed in court. Further, to the extent that government has failed or fails to establish the admissibility of any underlying data on which the summary charts are based, that evidence must be excluded and the defense will timely raise such an objection.

IV. FDA TESTIMONY AND EXHIBITS

The government has indicated it intends to call Dr. Susan Zullo from the FDA to speak about Arrayit's submission of application for EUA regarding its COVID-19 blood-test. The defense has previously objected in its motion in limine No. 3 to permitting testimony and evidence regarding the efficacy of Arrayit's COVID-19 test, including under FRE 401 and 403, and continues to do so. Additionally, it appears that the government may elicit testimony regarding the continuing discussions between FDA and Arrayit after charges were filed and up through June 22, 2022, when Arrayit withdrew its EUA application, as well as opinion testimony by Dr. Zullo about her hypothetical reaction to certain proferred facts. The activities and actions after June 9, 2020, are irrelevant for the reasons already briefed by the defense in its motion in limine No. 11. Further, identifying that Arrayit withdrew its application, especially without the full context that it did so because, despite providing information to the FDA, the FDA continued to change the criteria for evaluation, would be unduly prejudicial for the reasons previously briefed.

Indeed, the government has made clear that the case is not about the science of Arrayit's test but alleged statements about that test, among other things. The testimony from the FDA, if anything, relates to the former (*i.e.*, the nature of the test and the criteria FDA used in evaluating it), not the latter, and is thus inadmissible. As such, the Court should preclude testimony or evidence from the FDA about (1) the

interactions with Arrayit after June 9, 2020 and (2) its opinions, if any, as to the efficacy of Arrayit's test or how FDA might have acted under certain hypothetical scenarios.

V. CONCLUSION

For the reasons stated above, the Court limit or preclude the testimony in the manner as requested.

Respectfully submitted,

DATED: August 18, 2022

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By: */s/ Todd Pickles*
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